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INFORMED CONSENT:

Therapeutic hypothermia for children after in-hospital cardiac arrest not helpful

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ABSTRACT An informed consent discussion regarding the merits of therapeutic hypothermia in a comatose pediatric patient following in-hospital cardiac arrest and return of spontaneous circulation.

Keywords: *critical care, resuscitation, pediatrics*

Clinical Context

JC is a 14 year old male with no significant past medical history that presented to the emergency department this morning with altered mental status, fever, and nuchal rigidity for one day. JC returned home yesterday morning from a two week summer sports camp at a nearby university campus, where he was staying in the dorms with 200 other campers. Yesterday evening, he developed a fever of 104, together with a stiff neck and scattered petechiae over his abdomen. His parents decided to bring him to the emergency room after finding him difficult to arouse from sleep this morning. Upon evaluation in the emergency department, JC was found to have a blood pressure of 80/40, a white blood cell count of 23,000, and a lumbar puncture showing low glucose, many neutrophils, and gram negative diplococci. The ER resident initiated treatment for septic shock secondary to bacterial meningitis, and he was admitted to the pediatric ICU. Shortly after arriving in the ICU, JC developed profound bradycardia with a mean arterial pressure of 50 and loss of consciousness. Advanced cardiac life support was performed, starting with chest compressions, and ROSC was eventually obtained after five minutes. Although hemodynamically stabilized with reactive pupils and no abnormal posturing, JC has yet to regain consciousness, and there is concern for permanent neurological impairment secondary to anoxic brain damage.

Clinical Question

You are the pediatric critical care fellow taking care of JC. The family wishes to exhaust all possible medical avenues for the preservation of neurological function for JC, should he recover from his acute illness. The father says:

“I was listening to NPR the other week, and there was a segment where they talked about treating drowning victims by inducing hypothermia. The host said that researchers think this might help people whose brains have been starved of oxygen. Can we use hypothermia to help JC’s brain? He is so young and has so much to look forward to. I won’t be able to live with the thought that we didn’t do everything possible to help him.”

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Related Literature

To prepare for this informed consent, a literature search was performed using Google Scholar and the key words “therapeutic hypothermia pediatric cardiac arrest.” This generated a list of clinical trials and review articles, including a recent multicenter randomized control trial addressing the topic of therapeutic hypothermia for in-hospital cardiac arrest in pediatric patients.[1] Using the bibliography for this trial, two retrospective studies addressing the same topic were identified.[2] Additionally, a multicenter randomized control trial addressing out-of-hospital cardiac arrest in pediatric patients was identified.[3]

A PubMed search was initiated with the search terms "therapeutic hypothermia..." and the search engine auto-populated "therapeutic hypothermia cardiac arrest". The results of this search were limited to Clinical Trials, age birth-18, and Humans, resulting in 72 titles, all of which were reviewed for relevance to the clinical question. Titles reviewed were limited to in-hospital cardiac arrest. No additional studies were located.

Current guidelines recommend either 2 days of continuous hypothermia followed by three days of continuous normothermia or continuous normothermia for five days for comatose pediatric patients following in-hospital pediatric cardiac arrest with return of spontaneous circulation (ROSC).[4] The clinical question of this review asks whether the choice of hypothermia is the superior option.

The patient oriented outcome of interest can roughly be characterized as survival with preserved neurological function following recovery from acute illness and discharge from the hospital. There is some debate over how to define and measure neurological function in this clinical context. For the purposes of this review, it is best to use the standard set-forth in the most extensive clinical trial addressing this topic, Moler (2017), which uses the scoring system from the Vineland Adaptive Behavior Scales, second edition (VABS-II). Preservation of neurological function is thus equated to an age-corrected score of 70 or higher on the VABS-II test.

Doherty (2009) was a retrospective multi-center study assessing therapeutic hypothermia vs. normothermia for in hospital cardiac arrests in pediatric patients. Although this study found statistically significant associations between therapeutic hypothermia and mortality, the results were confounded by a failure of randomization: the sicker the patient, the more likely they were to receive therapeutic hypothermia. Fink (2010), another retrospective study, found no significant difference in in-hospital mortality between treatment groups, but suffered from similar issues with confounding. Additionally, no definitive data was reported on preservation of neurological function in either study.

Moler (2017) was a multi-center randomized control trial assessing therapeutic hypothermia as a treatment strategy for preserving long-term neurological function (one year post-treatment) in pediatric patients with return of spontaneous circulation (ROSC) after undergoing in-hospital cardiac arrest. Patients were randomized to a treatment or control group with therapy initiated within 6 hours of ROSC. Importantly, patients assigned to the control group were treated with cooling or warming techniques in order to maintain a physiologic state of normothermia. Thus, the true comparison was not between therapeutic hypothermia or nothing, but rather therapeutic hypothermia or therapeutic normothermia. The primary efficacy outcome of survival with age-corrected VABS-II score of 70 or higher one year post-treatment was achieved in 36% of patients in the treatment group vs. 39% of patients in the control group (relative risk 0.92, 95% confidence interval of 0.67 to 1.27). The trial was terminated early for futility after showing no significant difference between groups for the primary outcome.

Although patient characteristics differ for in-hospital cardiac arrest vs. out-of-hospital cardiac arrest, it is notable that Moler (2015), which addressed therapeutic hypothermia for neurological function preservation after out-of-hospital cardiac arrest found a similar lack of superiority between treatment and control.

Moler (2017) is the best available trial for addressing the clinical question. It is multi-center randomized control trial with a well-defined and clinically applicable primary end-point. It presents level 1 quality evidence for the non-superiority of therapeutic hypothermia compared to therapeutic normothermia in pediatric patients following in-hospital cardiac arrest and ROSC.[1,5,6,Supp.]

Informed Consent

Flesch-Kincaid Grade Level for the following passage is 7.0.

“Thank you for asking me about using hypothermia to treat JC.

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"It is true that doctors have been studying hypothermia. Some people think it might help preserve brain cells that have been oxygen starved. One study looked at this treatment for kids whose hearts stopped while in the hospital. It looked at kids of all different ages with all different types of illnesses.

"This study compared cooling to keeping patients at their normal body temperatures. It found no difference in neurological outcome.

"There is also some evidence from a smaller study that hypothermia may cause harm for kids like JC. He is in the hospital for a very dangerous condition. He was very sick before his heart stopped.

"In summary, I don't think it would be a good idea to use hypothermia for JC. The best evidence says that it doesn't provide a benefit. There is even some evidence that suggests it might worsen his condition. I recommend that we do what we can to keep him at his normal body temperature instead."

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